MORAN SUPPORTS PATHWAY FOR BIOSIMILARS ACT

Announces Co-Sponsorship of Important Biologics Legislation

WASHINGTON, D.C. - Congressman Jerry Moran this week announced his co-sponsorship of H.R. 1548, the Pathway for Biosimilars Act. HR 1548 would promote patient safety while supporting the development of biologics.

"I am proud to sponsor the Pathway for Biosimilars Act to support and foster the responsible development of important biologic medicines," Moran said. "Biopharmaceuticals represent a tremendous growth opportunity for our burgeoning bioscience industry in Kansas, and this legislation will help ensure that new biotechnology products continue to reach patients and medical professionals."

"KansasBio applauds Congressman Moran for being the first Kansas congressional member to co-sponsor the Pathway for Biosimilars Act, one of KansasBio's top congressional priorities for 2009," said Angela Kreps, KansasBio president. "This bill supports the work of more than 110 drug development companies in our state and their more than 10,000 employees, while also rigorously protecting patient safety."

Biologics are different from common prescription drugs that are synthesized through a chemical process. As biologics are living organisms, no one is ever exactly the same and each biologic can have very different effects on a patient. Therefore, it is important that legislation require that a follow-on biologic (FOB) demonstrate its similarity to the innovator product and maintain safety and efficacy.

HR 1548 would maintain patient safety by requiring the Food and Drug Administration (FDA) to conduct clinical trials for FOBs in order to demonstrate their safety and efficacy. Additionally, this bill would give the FDA limited waiver authority regarding the clinical trials in certain instances if the agency deems it overwhelmingly evident that the FOB and the innovator product are indeed identical. HR 1548 would also provide for a system of evaluating products for significant differences and risks to patient health before approving labeling that would make the FOB and innovator product interchangeable.

"As new biologics have the potential to fundamentally change the course of many diseases, it is critical that any legislation authorizing a pathway for follow-on biologics ensures patient safety while balancing the incentive to develop new medicines with the interest in savings through entry of FOBs in the health care marketplace," Moran continued. "This legislation will promote patient safety and ensure incentives to encourage the continued development of a critical weapon to fight diseases such as Alzheimer's, Parkinson's and cancer."

HR 1548 would incentivize the development of biologics by providing developers with an exclusivity period necessary to recoup their research and development costs and foster continued investment. Without this assurance, developers will not invest in bringing expensive FOBs to market.

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